FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product JEMPERLI (dostarlimab-gxly). JEMPERLI is indicated for the treatment of adult patients with mismatch repair deficient recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for JEMPERLI (U.S. Patent Nos. 9,815,897 and 10,738,117) from GlaxoSmithKline (agent for AnaptysBio, Inc.), and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 28, 2022, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of JEMPERLI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for JEMPERLI is 1,919 days. Of this time, 1,428 days occurred during the testing phase of the regulatory review period, while 491 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 22, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 22, 2016.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 19, 2019. FDA has verified the applicant's claims that the biologics license application (BLA) for JEMPERLI (BLA 761174) was initially submitted on December 19, 2019.

3. *The date the application was approved:* April 22, 2021. FDA has verified the applicant's claim that BLA 761174 was approved on April 22, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 355 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10361 Filed 5–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics (NCVHS) Meeting

AGENCY: National Committee on Vital and Health Statistics, Centers for Disease Control and Prevention.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain a link to attend this meeting by following the instructions posted on the Committee website: *https://ncvhs.hhs.gov/meetings/full-committee-meeting-18/*.

DATES: Wednesday, June 5, 2024: 11:00 a.m.–12:30 p.m. EDT.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Naomi Michaelis, MPA, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to *nmichaelis@cdc.gov*; or by telephone (301) 458–4202. Summaries of meetings and a roster of Committee members are available on the

NCVHS website *https://ncvhs.hhs.gov/*, where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[1] NCVHS advises the Secretary on administrative simplification standards, including those for privacy, security, adoption and implementation of transaction standards, unique identifiers, code sets, and operating rules adopted under the Patient Protection and Affordable Care Act (ACA).[2] Included in HIPAA is the statutory reporting requirement that the Committee submit to Congress and make public, a report regarding the implementation of part C of title XI of the Social Security Act.

The meeting agenda will include discussion of the NCVHS Report to Congress. The Committee will reserve time on the agenda for public comment. Meeting times and topics are subject to change. Please refer to the agenda posted on the NCVHS website for updates: *https://ncvhs.hhs.gov/meetings/full-committee-meeting-18/.*

Sharon Arnold,

Associate Deputy Assistant Secretary, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2024–10288 Filed 5–10–24; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute.

Date: July 8–9, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Cancer Institute, 9609 Medical Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian E. Wojcik, Ph.D., Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 3W414, Rockville, MD 20850, 240–276–5660, *wojcikb@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *https://deainfo.nci.nih.gov/advisory/bsc/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 7, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10293 Filed 5–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: June 13, 2024.

Time: 1:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Poonam Tewary, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20852, (301) 761–7219, *tewaryp@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 8, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10376 Filed 5–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

[1] Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at *https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf.*

[2] Public Law 111–148, 124 Stat. 119, available at *https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.*